Complete Summary

GUIDELINE TITLE

Hepatitis A virus.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Hepatitis A virus. New York (NY): New York State Department of Health; 2003 Mar. 2 p.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Hepatitis A virus (HAV) infection

GUIDELINE CATEGORY

Prevention Risk Assessment

CLINICAL SPECIALTY

Allergy and Immunology Family Practice Infectious Diseases Internal Medicine

INTENDED USERS

Health Care Providers Physician Assistants Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To develop guidelines for prevention of hepatitis A virus infection in human immunodeficiency virus (HIV)-infected patients

TARGET POPULATION

HIV-infected patients at risk for hepatitis A virus infection

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention

- 1. Risk assessment for hepatitis A infection
- 2. Hepatitis A vaccine
- 3. Combined hepatitis A and B vaccine
- 4. Post-vaccination antibody measurement (generally not recommended)
- 5. Post-exposure prophylaxis with immune globulin

MAJOR OUTCOMES CONSIDERED

- Effectiveness of hepatitis A (HAV) vaccines and immune globulin in preventing infection
- Incidence of HAV infection and complications
- HAV viral load in human immunodeficiency virus (HIV)-infected individuals

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVI DENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person 3-4 times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Prevention of Hepatitis A virus (HAV) Infection

Clinicians should offer the hepatitis A vaccine to patients who are at increased risk of hepatitis A infection:

- Persons with chronic liver disease (e.g., hepatitis B or C)
- Men who have sex with men
- Travelers to countries with high endemicity of infection
- Persons who live in a community experiencing an outbreak of HAV infection
- Illicit drug users, particularly injection drug users
- Persons who have clotting-factor disorders
- Persons at occupational risk for infection

The full series should be given (initial dose and a second dose 6 to 12 months later) to ensure maximal antibody response.

Non-immune patients who are at increased risk for both hepatitis A and hepatitis B infection may be given the combined hepatitis A and B vaccine in a total of three doses at 0, 1, and 6 months.

Clinicians should administer HAV vaccination early in the course of human immunodeficiency virus (HIV) infection. If a patient's CD4 count is <300 cells/mm³ or the patient has symptomatic HIV disease, it is preferable to defer vaccination until several months after initiation of antiretroviral (ARV) therapy in an attempt to maximize the antibody response to the vaccine.

Routine post-vaccination antibody measurement is not recommended because of the generally high efficacy of the vaccine.

Clinicians should administer HAV post-exposure prophylaxis to HAV susceptible patients (i.e., non-immune or non-vaccinated) with immune globulin (0.02 mL/kg IM) within 2 weeks of exposure. HAV vaccine is not indicated for post-exposure prophylaxis, although it is prudent to administer it concurrently with serum immune globulin for the long-term prophylaxis of an at-risk individual.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not stated.

POTENTIAL BENEFITS

- Appropriate management of human immunodeficiency virus (HIV)-infected patients at risk for hepatitis A virus (HAV) infection.
- Infection with HAV can be prevented by active immunization prior to exposure with either of the two currently licensed vaccines, which are considered equivalent in efficacy.
- Serum immune globulin can be given to individuals who are not immune to HAV within 2 weeks after an exposure to an HAV household contact, sexual partner, or common source exposure. A single intramuscular dose of 0.02 cc/kg is effective in preventing infection or attenuating HAV infection that might result from such an exposure.

POTENTIAL HARMS

Not stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening, or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (HIV clinical practice guidelines, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience
- Define target audience (providers, consumers, support service providers)

Are there groups within this audience that need to be identified and approached with different strategies? (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)

Define implementation methods

What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?

- Determine appropriate implementation processes
 - What steps need to be taken to make these activities happen?
 - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?
 - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
 - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor Progress

What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?

- Evaluate
 - Did the processes and strategies work? Were the guidelines implemented?
 - What could be improved in future endeavors?

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Hepatitis A virus. New York (NY): New York State Department of Health; 2003 Mar. 2 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Mar

GUI DELI NE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Medical Care Criteria Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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Liaisons: Sheldon Brown, MD; Barbara Chaffee, MD, MPH; Joseph R. Masci, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>New York State Department of Health AIDS Institute Web site</u>.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p.

Electronic copies: Available from the <u>New York State Department of Health AIDS</u> <u>Institute Web site</u>.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108.

PATIENT RESOURCES

None available

NGC STATUS

This summary was prepared by ECRI on January 22, 2004.

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